UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS

IN RE REPROS THERAPEUTICS, INC. SECURITIES LITIGATION	**Civil Action No. 09 Civ. 2530(VDG)**

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION
TO DISMISS THE CONSOLIDATED CLASS ACTION COMPLAINT

NATURE AND STAGE OF THE PROCEEDING

On January 27, 2010, Lead Plaintiff Raymond Wong and plaintiff Jim Chen filed a Consolidated Class Action Complaint ("CCAC") in the above captioned putative class action (the "Action"), alleging federal securities law violations against Repros Therapeutics, Inc. ("Repros" or the "Company") and certain of its officers and/or directors, on behalf of a class (the "Class") of all persons who purchased or acquired common shares of Repros between July 1, 2009 and August 2, 2009 (the "Class Period"). The CCAC alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5). On March 15, 2010, Defendants moved to dismiss the CCAC under Fed. R. Civ. P. 12(b)(6). Plaintiffs submit this memorandum in opposition to Defendants' motion.

SUMMARY OF THE ARGUMENT

This Action concerns Defendants' misstatements to investors regarding clinical trials on Repros's key product, Proellex. On July 1, 2009, Defendants informed investors that while patients taking Proellex in 50 mg doses showed elevated liver enzymes, the 50 mg dose showed no increase in efficacy over smaller doses, so Proellex would no longer be administered in a 50 mg dose, but it would continue at the 25 mg and 12.5 mg doses. During the next 33 days, Defendants reassured investors that Proellex was "well tolerated" and had an improved "safety profile" in the 25 mg and 12.5 mg doses. On August 3, 2009, Defendants reversed their position on Proellex and announced the cancellation of all clinical trials due to safety concerns regarding elevated liver enzymes associated with all doses.

The misstatements regarding the safety of Proellex were made with the requisite scienter because they were made either knowingly or with reckless disregard for the truth and lacked a

basis in fact. Despite Defendants' attempts to recast this Action as one in which Plaintiffs allege that the safety and eventual approval of Proellex was guaranteed, Plaintiffs allege nothing of the sort. Defendants admit that during the Class Period "the company was analyzing data as it became available and disclosing the results as that analysis was completed," so the fact that they made affirmative statements regarding the safety of the lower doses when they lacked a basis to do so constitutes at least severe recklessness. Defendants were receiving clinical data in electronic form in real time, and the Individual Defendants, who constituted 30% of Repros's work force, would by necessity receive and be capable of interpreting this data concerning the key product on which the future of the Company depended.

Defendants' scienter is further demonstrated by their motive. Defendants had a desperate need to obtain financing immediately and extend a key contract, and could only do this if Proellex was viewed as a viable product. While issuing misstatements could harm Defendants at some point in the future, "[t]his approach could provide Repros with a stay of execution and could buy Defendants some additional time to deal with funding issues." The unique timing of Repros's eleventh-hour financing attempts further supports a compelling inference of scienter.

STATEMENT OF ISSUES

1. Did Defendants make material misstatements by informing investors that Repros's drug Proellex was "well tolerated" and that the 25 mg and 12.5 mg doses would improve the "safety profile" of Proellex, despite the fact that, 33 days after these statements were made, Repros reversed its position on the safety of Proellex and cancelled all clinical trials of Proellex due to issues with elevated liver enzymes?

2. Did Defendants act with the requisite scienter when:

   a. Defendants falsely stated Proellex was "well tolerated" and that the 25 mg and

12.5 mg doses would improve the "safety profile" of Proellex, despite the fact that they either (i) expressly knew that such statements were unsupportable or (ii) lacked sufficient information about the elevated liver enzymes and thus lacked a basis to make such statements;

b. Defendants had a specific motive to issue false news about Proellex, at least in the short term, because the truth about Proellex would jeopardize their attempts to adhere to a key agreement and to obtain immediate short-term funding necessary to save the Company; and

c. the Individual Defendants knew or were reckless in not knowing about problems with Proellex because they were involved in the day-to-day details of running the Company, Repros was a small company with no more than ten employees during the Class Period, and Proellex was Repros's key product?

3. Have Plaintiffs alleged that the Individual Defendants acted as "control persons" for purposes of establishing liability under Section 20(a) of the Exchange Act?

STANDARD OF REVIEW

Defendants have moved to dismiss the CCAC under Rule 12(b)(6) of the Federal Rules of Civil Procedure, which permits the dismissal of a complaint only for "failure to state a claim upon which relief can be granted." To avoid dismissal, a complaint must allege "enough facts to state a claim to relief that is plausible in its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A complaint "attacked by a Rule 12(b)(6)**Error! Bookmark not defined.** motion to dismiss does not need detailed factual allegations," but rather must simply provide the grounds of entitlement to relief and raise a right to relief above the speculative level. *Id.* at 555.

A plaintiff must prove the following five elements for a Section 10 (b) cause of action: (1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss. *Dura*

Pharms., Inc. v. Broudo, 544 U.S. 336, 341-42 (2005). Defendants do not contest the last three elements – they argue only that Plaintiffs have not adequately pled a material misrepresentation or scienter.

In addition, for each misleading statement, a plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). "The required state of mind is an intent to deceive, manipulate or defraud or severe recklessness." *Indiana Elec. Workers' Pension Trust Fund IBEW v. Shaw Group, Inc.*, 537 F.3d 527, 533 (5th Cir. 2008). A plaintiff "must plead facts rendering an inference of scienter at least as likely as any plausible opposing inference." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 328 (2007). As this Court has noted, scienter allegations must be viewed under the "totality of the circumstances." *In re Seitel, Inc. Sec. Litig.*, 447 F. Supp. 2d 693, 709 (S.D. Tex. 2006).

FACTS

Repros is a "development stage biopharmaceutical company" that develops "oral small molecule drugs for major unmet medical needs that treat male and female reproductive disorders." ¶ 22. ("¶ __" refers to paragraphs in the Consolidated Amended Complaint.) During the Class Period, its main product, Proellex, was in clinical trials[1] and was developed to treat three

[1] Repros was conducting three clinical trials on Repros. Two trials, on patients with symptoms associated with uterine fibroids and anemia associated with uterine fibroids, had completed the "Phase 2" stage and proceeded to the more advanced "Phase 3" stage. The other trial on patients with symptoms associated with endometriosis, had completed the "Phase 2" stage in January 2009. Thus, by the start of the Class Period, each of the three clinical trials had completed the Phase 2 stage. ¶ 26.

Phase 1 trials are initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness. Phase 2 trials are controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condi-

medical problems: (1) anemia associated with uterine fibroids; (2) treatment of chronic symptoms associated with uterine fibroids; and (3) treatment of chronic symptoms associated with endometriosis. ¶ 23.

Proellex was not invented by Repros. Starting in 1999, Repros licensed Proellex from the National Institute of Health ("NIH"), in accordance with a license agreement that has been amended over time (the "License Agreement"). The License Agreement gives Repros the rights to develop Proellex, and in turn, Repros must pay the NIH a licensing fee and must meet various milestones for the commercial development of Proellex, including eventual approval by the FDA. If these milestones are not met, the NIH could revoke the License Agreement, causing Repros to lose its key product. ¶ 25.

A. Repros's Financial Health Was Dependent on The Success of Proellex

By the middle of 2009, Repros's financial viability was tenuous at best. Repros stated in its 2008 10-K that "[w]e expect our current capital to be sufficient to fund our operations through at least the second quarter of 2009, depending on the timing and success of our clinical trials. Thereafter, we will need to seek additional funding through public or private financings, including equity and debt financings, and/or through other means, including collaborations and licensing agreements." ¶ 32. Furthermore, on July 7, 2009, Repros and the NIH entered into an amendment to the License Agreement providing that, by September 30, 2009, Repros must "[o]btain financing, upfront licensing consideration, or any combination thereof . . . of no less than a combined total of Six Million Dollars ($6,000,000)." ¶ 33.

---

tion under study and to determine the common short-term side effects and risks. Phase 3 trials are expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling. ¶ 27.

Because Repros was running out of capital, and had a deadline from the NIH, it would need to attract additional investment during the third quarter of 2009 in order to survive, even in the short term. If Repros issued negative news on Proellex, any possibility of additional investment could be jeopardized. ¶ 34. In fact, Defendants admitted that any delay in the commercial development of Proellex could doom the Company. Repros stated in its 2008 10-K that "[i]f we delay or abandon our development efforts related to Proellex or Androxal, we may not be able to generate sufficient revenues to continue operations or become profitable." ¶ 35.

B. Repros's Misstatements Regarding Proellex

On July 1, 2009, the beginning of the Class Period, Repros announced an update to the supposed results of the Phase 2 trial, and issued a press release (the "July 1 Release") stating that the results of the trial showed "no efficacy differences between the 25 mg and 50 mg doses." ¶ 38. Further down, several paragraphs later, the July 1 Release mentioned that the 50 mg doses would be discontinued due to "an observed dose-dependent increase in liver enzymes in a low percentage of women." *Id*. Nonetheless, the July 1 Release stated that "it has been determined that the drug is well tolerated with few women discontinuing treatment due to adverse events." *Id*. Thus, according to the July 1 Release, the 25 mg dose was just as effective as the 50 mg dose, and the 50 mg dose was discontinued due to increased liver enzymes at that dose, but Proellex was still "well tolerated," with only a few women discontinuing treatment.

Six days later, Repros issued another release (the "July 7 Release") which stated that while the 50 mg dose had been discontinued due to an observed increase in liver enzymes in some trial participants, "[t]he company believes that the 25 mg and 12.5 mg doses will offer comparable efficacy benefits while providing an improved safety profile." ¶ 38.

Sixteen days after that, the truth about Proellex was partially revealed when Repros is-

sued a press release (the "July 23 Release") stating that several patients who had received the 50 mg dose suffered elevated liver enzymes so great that they "had their treatment stopped and have been referred to an appropriate specialist for further evaluation." In spite of this, Defendants stated that "Repros believes that the decision to move forward with the 25 mg and 12.5 mg doses will improve the benefit/risk profile of Proellex." *Id.*

By the end of July, Defendants realized that they could no longer conceal all of the information regarding Proellex's risk of elevated liver enzymes in all doses, and they would be forced to reveal these risks to the FDA, and in turn they knew such information would be made public. Before the market opened on August 3, 2009, only 33 days after Repros issued its press release minimizing the negative results of the Phase II trial for patients with endometriosis, Repros issued a press release (the "August 3 Release") announcing the suspension of all Proellex clinical trials, based on a clinically significant increase in liver enzymes among participants. ¶ 51. As a result, on August 3, 2009, Repros's stock closed at $1.31, a 48% drop from a close of $2.53 the trading day before. Overall, this represented a 73% drop from the close of $4.96 on July 1, 2009. ¶ 53.

On August 6, 2009, Repros was forced to reveal, in a press release over BUSINESS WIRE, that the FDA was placing Proellex on a clinical hold for safety reasons. ¶ 54. On September 16, 2009, Defendant Ploth was removed as Chief Financial Officer, and on October 29, 2009, Defendant Lammers resigned as President. ¶ 55.

ARGUMENT

I. DEFENDANTS' STATEMENTS WERE MATERIALLY FALSE AND MISLEADING

On July 1, 2009, Defendants issued a press release stating that Proellex was "well tolerated" and/or that they believed that the 25 mg and 12.5 mg doses were safe. The safety of the

lower doses was reiterated in press releases issued on July 7, 2009 and July 23, 2009. However, on August 3, 2009, 33 days after the July 1 Release was issued, Defendants reversed their position on the safety of Proellex and were forced to cancel all clinical trials on Proellex. As demonstrated below, Defendants' statements about the safety of the 25 mg and 12.5 mg doses were false and misleading, in violation of Section 10(b).

A. The July 1 Release

In the July 1 Release, Defendants falsely stated that Proellex is "well tolerated." ¶ 38. This was materially misleading. Only 33 days after this statement was issued, it was revealed that patients enrolled in the Proellex clinical trials suffered liver enzyme increases so severe that they had to be referred to specialists for evaluation. ¶ 46. The magnitude of this safety risk hardly indicates that Proellex was "well tolerated."

Defendants downplay this issue, suggesting that the "well tolerated" language could be reconciled "with the discovery of liver enzyme issues in a low percentage of patients." Def. Br. at 9. (Def. Br. refers to Defendants' brief in support of their motion to dismiss.) A drug is not considered "well tolerated" merely because a majority of patients do not suffer dangerous side effects. Drugs are not considered safe, and are not approved by the FDA, merely because most patients do not suffer dangerous side effects. Defendants' statement that Proellex was "well tolerated" provided investors with unwarranted reassurance about the safety of the drug. Other courts have found that a statement that a drug is "well tolerated" can be false and misleading when there are adverse effects from usage. *See In re Connetics Corp. Sec. Litig.*, No. C. 07-02940 SI, 2008 WL 3842938, at *6 (N.D. Cal. Aug. 14, 2008) (statement that drug was "safe and well tolerated" was misleading when it was contradicted by results of a mouse study demonstrating potential carcinogenic effects) (attached as Exhibit 1 to the Compendium of Unreported Cas-

es ("Compendium") submitted herewith); *In re Regeneron Pharms Sec. Litig.*, No. 94 Civ. 1785 (CLB), 1995 WL 228336, at *6 (S.D.N.Y. Mar. 10, 1995) (on motion for summary judgment, a drug's toxic side effects raised issue of fact as to whether statements that the drug was "safe and well tolerated" was false and misleading) (Compendium Ex. 2).

Furthermore, the first paragraph of the July 1 Release leads off with the news that there were "no efficacy differences between the 25 mg and 50 mg doses." ¶ 38. It is not until several paragraphs later that the July 1 Release mentions that the 50 mg doses will be discontinued due to "an observed dose-dependent increase in liver enzymes in a low percentage of women." *Id.* Thus, while the press release mentioned elevated liver enzymes associated with the 50 mg dose, it assured investors that those issues had little relevance because the 50 mg doses were nevertheless being discontinued due to a lack of increased efficacy. The July 1 Release says nothing about an increase in liver enzymes at 25 mg and 12.5 mg, and the implication is there is none.

B. The July 7 and July 23 Releases

Similarly, in the July 7, 2010 Release, Defendants falsely stated that Repros reasonably believed that "the 25 mg and 12.5 mg doses will offer comparable efficacy benefits while providing an improved safety profile." ¶ 42. Further, in the July 23 Release, Defendants stated that "Repros believes that the decision to move forward with the 25 mg and 12.5 mg doses will improve the benefit/risk profile of Proellex."

However, Defendants' "belief" in the safety of the 25 mg and 12.5 mg doses of Proellex was not legitimately held, and therefore their statement are actionable. "For securities fraud cases, an opinion or prediction is actionable if there is a gross disparity between prediction and fact." *Lormand v. US Unwired, Inc.*, 565 F.3d 228, 248 n.13 (5th Cir. 2009). Such a gross disparity between Defendants' statements and reality is supported by the fact that it took less than

one month from the July 7 Release for Defendants to completely reverse themselves and suspend clinical trials on all doses, including the 25 mg and 12.5 mg doses. "Opinions" about clinical trials can be actionable if they are made without a reasonable basis in fact. *In re Amylin Pharms. Inc. Sec. Litig.*, No. 01CV1455 BTM (NLS), 2003 WL 21500525, at *9 (S.D. Cal. May 1, 2003) (opinion about sufficiency of clinical trial actionable when contradicted by information shared in contemporaneous meeting with FDA) (Compendium Ex. 3).[2]

C. Cautionary Language Does Not Render Defendants' Statements Immaterial

Defendants point to cautionary language in the 2008 10-K[3] and the July 1, 7 and 23 Releases concerning the fact that, because Proellex was in clinical trials, the then-current data could be superseded by new data showing problems with Proellex's efficacy or safety. Def. Br. at 4, 13-14. This is a red herring. Plaintiffs do not dispute that clinical trials can produce unexpected and disappointing results. However, the cautionary language does not warn against the specific misconduct here – that Defendants knew or were reckless in not knowing of issues with elevated liver enzymes, yet issued statements regarding the safety of Proellex at lower doses that either they knew were false or had no basis in fact. *See In re Regeneron Pharm. Inc. Sec. Litig.*, No. 03

[2] These allegations are not, as Defendants argue, "fraud by hindsight." Def. Br. at 16. For the reasons discussed above, at the time the Defendants made the misstatements in the July 1, 7, and 23 Releases, they either knew that the statements were false, or they made the statement with reckless disregard as to whether or not they were true. *See Lormand*, 565 F.3d at 254 (allegations of defendants "state-of-mind at the time of their misleading statements and omissions" did not amount to fraud-by-hindsight).

[3] Repros's 10-K was filed on March 16, 2009, yet the Class Period does not begin until July 1, 2009. Defendants' statements made in March 2009 regarding potential problems with clinical trials have no bearing in July 2009, by which time Defendants knew or were reckless in not knowing of the extent of the problems with liver enzymes but made statements as to Proellex's safety without a basis in fact. Similarly, Defendants cite to the cautionary language in the July 7 Release regarding plans to initiate studies in the fourth quarter of 2009 and first quarter of 2010. This provides no assurance to an investor that the clinical trial which took place by July already demonstrated elevated liver enzymes associated with all doses.

Civ. 3111(RWS), 2005 WL 225288, at *18-19 (S.D.N.Y. Feb. 1, 2005) (cautionary language provided no protection when it "does not adequately disclose actual problems that already have materialized" and did not "refer to any of the specific problems concerning [the drug at issue] that are detailed in the Amended Complaint and that [defendant] allegedly knew to exist at the time the statements at issue were made") (Compendium Ex. 4).

II. PLAINTIFFS HAVE ESTABLISHED A STRONG INFERENCE OF SCIENTER

Defendants acted with the requisite scienter because, as detailed below, during the Class Period they issued misstatements about the safety of Proellex either knowingly or with a severely reckless disregard for the truth. Defendants did so because Repros was in grave danger of failing, and revelations of the true risks of Proellex would jeopardize attempts to get the short-term funding the Company needed to survive.

A. Defendants' Statements About the Safety Of the Smaller Doses Of Proellex Were Made Knowingly Or With Reckless Disregard For The Truth

Defendants argue Plaintiffs fail to allege that "any Defendant believed during the Class Period that the liver enzymes issue affecting a small percentage of patients taking the 50 mg dose also jeopardized the 25 mg and 12.5 mg doses." Def. Br. at 12. Defendants' scienter can be inferred from various factors. By the end of the Class Period, Defendants had information showing that elevated liver enzymes posed such a risk that clinical trials for all doses had to be stopped. Nevertheless, during the previous 33 days, they repeatedly assured investors that, despite the fact that the 50 mg dose caused unacceptably high liver enzyme levels, patients taking 25 mg or 12.5 mg doses were not at risk. During the Class Period, Defendants either had the data in hand showing the elevated liver enzymes at the smaller doses or had insufficient data to opine either way on the safety of Proellex.

During the Class Period, Defendants were reading and analyzing the clinical data and

should have had data sufficient to show the true risks of Proellex regarding elevated liver enzymes. If they had the data, they knowingly misled investors that patients taking 25 mg or 12.5 mg doses were safe.

Alternatively, it is possible, as Defendants champion, that during the Class Period Defendants did not have complete knowledge about the extent of the elevated liver enzymes associated with the smaller doses, but "the company was analyzing data as it became available and disclosing the results as that analysis was completed." Def. Br. at 14. If true, this scenario also provides an inference of scienter. If during the Class Period Defendants had an incomplete set of safety data regarding the liver enzyme issue, then they lacked the data to make affirmative representations about the safety of the smaller doses. Thus, because Defendants knew that the 50 mg dose of Proellex caused unacceptably high liver enzymes, and Defendants did not have adequate information about the liver enzyme issues at smaller doses, they were severely reckless in making the affirmative representations in the July 1, 7, and 23 Releases that the 25 mg and 12.5 mg doses were still safe.

Accordingly, despite Defendants' unsupported claim that they should be entitled to the inference that they had an "informed belief that . . . the drug would continue to move forward at the lower dose levels," Def. Br. at 16, the more plausible inference, given the quick and complete reversal of their statement about the safety of the lower doses, is that Defendants either did not believe such statements at the time they were made, or that Defendants acted with severe recklessness in making such statements without a basis in fact. *See In re Neopharm, Inc. Sec. Litig*., No. 02 C 2976, 2003 WL 262369, at *11 (N.D. Ill. Feb. 7, 2003) (information as to whether company was aware of Phase II test results likely only in control of defendants and plaintiff pled enough facts to warrant inference defendants were aware) (Compendium Ex. 5).

Plaintiffs describe the electronic data capture system ("EDCS") in the CCAC to demonstrate that Defendants had almost instantaneous access to the medical data of trial participants. Defendants argue that "the mere existence of the EDCS is insufficient to raise an inference of scienter." Def. Br. at 14. Defendants' argument that Plaintiff's were required to facts regarding who specifically saw such data is nonsensical. The Individual Defendants were three key officers of a ten-person company. Who would see and comprehend the data if not them? Furthermore, if Defendants were not reviewing and comprehending the available real-time data, it is the height of recklessness to make statements about the clinical trials and safety of Proellex.

B. Defendants' Consultation With A Panel Of Liver Experts Does Not Exculpate Them

Defendants argue that they "took the appropriate steps of conferring with a panel of liver experts." Def. Br. at 15. However, according to the August 3 Release, the panel of liver experts was consulted "recent[ly]". ¶ 51. While Defendants deemed it necessary to consult an expert panel about the safety of Proellex, this did not stop them from making earlier affirmative representations that the 25 mg and 12.5 mg doses were safe in the July 1, 7, and 23 Releases, presumably before the expert panel had any input. Contrary to Defendants' assertions, the belated consultation with liver experts does not support the inference that Defendants acted properly. Rather, it supports the inference that Defendants knowingly or recklessly issued falsely positive news, and then consulted experts only after the fact.

C. The Short Time Period Between The False Statements And The Revelation Of the Truth Demonstrates Scienter

The short 33 day time frame between Defendants' first misstatements regarding elevated liver enzymes and the termination of clinical trials of Proellex supports the inference that Defendants made statements about the safety of 25 mg and 12.5 mg doses with at least severely reckless, if not intentional, disregard for the truth. It is possible that Defendants could receive unex-

pected data about elevated liver enzymes associated with Proellex, and it would take Defendants 33 days to analyze the data and confer with experts to determine the extent of the liver issues, and ascertain whether those problems were also present in lower doses. However, it is the definition of recklessness to make the statements regarding the safety of the drug while analysis is still taking place.[4]

Once Defendants discussed the safety of the 25 and 12.5 mg doses, they had a duty to do so truthfully and with a reasonable basis. *Rubenstein v. Collins*, 20 F.3d 160, 170 (5th Cir. 1994). When Defendants became aware of the liver enzyme issues, they could have said something similar to the following: "While there are elevated liver enzymes associated with the 50 mg dose of Proellex, over the next several weeks we will determine whether this risk is present in the lower doses. We will update you when we have consulted liver experts and have more information." However, rather than refraining on commenting about the safety of the lower doses until all the facts and analysis were available, Defendants jumped the gun and made state-

[4] Defendants cite two cases for the proposition that the failure of a clinical trial does not impute earlier knowledge of negative information. Def. Br. at 16-17. Plaintiffs' allegations are based on much more than the mere failure of a clinical trial. In *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC, Inc.*, 537 F.3d 35, 41 (1st Cir. 2008), the class period ran for over a year and the court found that defendants were not aware of problems until ten days before the end of the Class Period when Biogen senior officers were informed of the deaths of two patients in the trial. By contrast, in this Action, Plaintiffs have alleged that Defendants knew or were reckless in not knowing about the true risks regarding elevated liver enzymes during the 33 day Class Period, yet they continued to tout the safety of 25 mg and 12.5 mg doses of Proellex in three press releases during this time.

Similarly, in *In re Pfizer, Inc. Securities Litigation*, 538 F. Supp. 2d 621, 626 (S.D.N.Y. 2008), a cholesterol drug's clinical trials were stopped due to safety issues. Plaintiffs unsuccessfully argued that the health risks were concealed from investors. However, in that case, well before the class period, a previous trial showed an increase in blood pressure among trial participants, and investors were on notice of this even before the start of the class period. Here, by contrast, investors were unaware of any elevated liver enzyme issues until the start of the Class Period, and even during the Class Period such risks were understated by Defendants.

ments about the safety of these doses, only to completely reverse themselves a short time later. Defendants' desire to make such positive statements during this 33 day period, only to reverse themselves at the end of the Class Period, provides a compelling inference that Defendants are at least severely reckless in making their statements. Courts will infer scienter from a short time period between the misstatement and the disclosure of the fraud. *See Mississippi Pub. Employees Ret. Sys. v. Boston Scientific Corp.*, 523 F.3d 75, 91 (1st Cir. 2008) ("[t]he extremely short time period [between the statement and the revelation of the truth] is strong evidence" of scienter).

D. The Individual Defendants' Positions At Repros, The Small Size Of The Company, And The Fact That Proellex Was A Key Product Support An Inference Of Scienter

Defendants argue that "Plaintiffs have not pleaded facts demonstrating that any Individual Defendant was aware of any information apart from that reflected in Repros's disclosures." Def. Br. at 15. The Individual Defendants' scienter is supported not only by their positions at Repros, but also by the small size of Repros and the fact that Proellex was its key product. However, Plaintiffs base their allegations against the Individual Defendants on much more than just their positions as executives, and have demonstrated that each Individual Defendant had detailed knowledge of the issues with Proellex.[5]

1. Proellex Was The Company's Key Product

"Proellex was Repros's key product, and the safety of Proellex was crucial to the survival of the company." ¶ 14. The fact that misstatements concern a company's key product can demonstrate knowledge by the key officers of that company. In *Nathenson v. Zonagen*, 267 F.3d 400

[5] The fact that Ploth and Lammers both left the company soon after truth was revealed provides additional evidence of scienter. *See In re Adaptive Broadband Sec. Litig.*, No. C-01-1092 SC, 2002 WL 989478, at *14 (N.D. Cal. Apr. 2, 2002) (the fact that officers resigned "add[s] one more piece to the scienter puzzle") (Compendium Ex. 6).

(5th Cir. 2001), the plaintiffs alleged, among other things, that the defendants made a number of misrepresentations regarding Zonagen's potential products, Vasomax and Immumax, in order to artificially inflate the company's stock price. Among the special circumstances considered by the court in finding scienter was the fact that "Zonagen was essentially a one product company, and that product was Vasomax." *Id.* at 425. Similarly, in *In re Viropharma, Inc.*, No. CIV. A. 02-1627, 2003 WL 1824914, at *9 (E.D. Pa. Apr. 7, 2003) a case concerning misstatements about the efficacy and safety of a drug in Phase 2 and 3 trials, individual defendants were found to possess the requisite scienter because, among other things, the drug was "Viropharma's leading product and Defendants were the highest ranking members of the company, [and] it can be assumed that the Defendants were aware of these facts." (Compendium Ex. 7.)

2. Repros Was A Small Company

Repros had only ten employees during the Class Period. The small size of a company can also provide the inference that officers should have known of key issues within the company. In *Nathenson,* the Fifth Circuit noted that a company of thirty-five full time employees was "not large," and found that fact supports a strong inference of scienter. 267 F.3d at 425; *see also Backe v. Novatel Wireless, Inc*., 642 F. Supp. 2d 1169, 1186 (S.D. Cal. 2009) (scienter supported by fact that defendants held key positions in the company and were involved in day-to-day operations). Here, Repros was one-third the size of Zonagen. Accordingly, due to the small size of Repros, coupled with the fact that Proellex was Repros's key product, each Individual Defendant's job would entail extensive involvement with Proellex's clinical trials, and the problems arising therefrom.

3. Podolski And Lammers Were Very Familiar With Proellex's Clinical Trials

Knowledge of a small company's key product can be imputed to a company's highest

ranking members. *In re Viropharma, Inc.*, No. CIV. A. 02-1627, 2003 WL 1824914, at *9 (E.D. Pa. Apr. 7, 2003) (knowledge can be imputed to defendants who were highest ranking members of company). Both Podolski and Lammers participated in a year-end earnings conference call in March 2009, where they both discussed, in detail, the results of the Proellex clinical trials. ¶ 31. Defendant Lammers was specifically hired in February 2009 to guide Repros through the regulatory process in bringing Proellex to market. *Id.* This demonstrates that both Podolski and Lammers had a detailed knowledge of the clinical trials and would thus have any knowledge about any liver enzyme issues. *See Regeneron*, 2005 WL 225288, at *23-24 (day-to-day supervision of drug development program by defendants a factor in finding scienter was adequately alleged); *In re Genta, Inc., Sec. Litig.*, No. Civ. A. 04-2123(JAG), 2005 WL 2416970, at *6 (D.N.J. Sept. 30, 2005) (comprehensive knowledge of clinical trials can be reasonably imputed to defendant who is president, chairman, and CEO) (Compendium Ex. 8).

E. Plaintiffs Have Demonstrated Additional Evidence Of Scienter Through Motive

Under the Fifth Circuit's standards for pleading scienter, motive and opportunity allegations may "meaningfully enhance the strength of the inference of scienter." *Indiana Elec. Workers' Pension Trust Fund IBEW v. Shaw Group, Inc.*, 537 F.3d 527, 533 (5th Cir. 2008). The scienter allegations discussed above are further strengthened by specific allegations regarding Defendants' motive to conceal the truth about elevated liver enzymes, at least in the short term, to maximize their chances of receiving essential funding and extend the License Agreement.

Contrary to Defendants' arguments in Def. Br. at 19-20, Plaintiffs' scienter allegations are not based solely on motives common to all corporate executives. In fact, Plaintiffs allege that Defendants' motives were based on Repros's specific needs. After the second quarter of 2009, Repros was in significant danger of running out of capital absent additional funding. ¶ 32. Fur-

thermore, the NIH imposed a deadline requiring Repros to obtain $6 million in financing by September 30, 2009, or else Repros's License Agreement would be in jeopardy. ¶ 33. [6] Accordingly, Repros had a very short timeframe to obtain this financing, and negative news on Proellex would jeopardize its ability to do so, possibly causing Repros to fail.

While the general motive to raise capital is shared by all corporate executives and does not adequately demonstrate scienter, courts in this Circuit have found the requisite strong inference of scienter where a company's future prospects depended substantially on the success of a product about which false or misleading statements were allegedly made, or on the completion of an event "crucial" to the well-being or survival of the company. [7] *See, e.g.*, *Nathenson*, 267 F.3d at 425 (dependence of a company's future prospects on the success of a potential drug supports a strong inference of scienter on the part of the company and Defendant Podolski, who was actual-

[6] Defendants note that the sixth amendment to the licensing agreement was executed on July 7, 2009 and suggest that this means that the September 30, 2009 deadline to obtain financing "*did not exist*" when the class period began on July 1, 2009. Def. Br. at 19. Plaintiffs submit that it is unlikely that the amended agreement was negotiated, drafted, and executed on the same day – particularly as the agreement required one party to raise a substantial amount of capital in a short period. In fact, the CCAC alleges that the Sixth Amended Licensing Agreement was executed "*after negotiations*." ¶ 33.

[7] Defendants cite *In re Vertex Pharms. Inc. Sec. Litig.*, 357 F. Supp. 2d 343, 354 (D. Mass. 2005), and *In re Discovery Labs Sec. Litig.*, No. 06-1820, 2006 WL 3227767, at *14 (E.D. Pa. Nov. 1, 2006) (Compendium Ex. 9) for the proposition that financial motives are not sufficient to show scienter. Both cases are distinguishable from this Action. In *Vertex*, the court found the plaintiffs' overall allegations, taken together, failed to create a strong inference of scienter, even though allegations of financial motive strengthened the inference. 357 F. Supp. 2d at 354. However, unlike in this Action where Proellex was Repros's key, "make or break" product, the alleged misstatements at issue in *Vertex* involved one drug of many that the company was developing and intended to bring to market. *See id*. at 349. Further, the merger at issue in *Vertex* was not crucial to the company's survival. Similarly, in *Discovery Labs*, the court found that the plaintiffs' allegations of the company's financial motives – to raise $8 million in financing – were insufficient to support the required inference of scienter, because the financing was not needed for the survival of the company. In contrast, the ability to obtain financing alleged as motive in this Action was crucial to Repros's survival.

ly Zonagen's CEO at the time); *Goldstein v. MCI WorldCom*, 340 F.3d 238, 250 (5th Cir. 2003) (the plaintiffs' allegations of the company's need to complete a "crucial" merger were sufficient to plead motive).

Defendants had a desperate need to obtain the financing immediately, and could only do so if they knowingly or recklessly issued statements about Proellex's safety in smaller doses. While issuing misstatements could harm Defendants at some point in the future, "[t]his approach could provide Repros with a stay of execution and could buy Defendants some additional time to deal with funding issues." ¶ 37. Defendants viewed the issuance of such statements as a better option than telling the truth, which could cause the company to fail. If Defendants were merely severely reckless in issuing such information, and it indeed turned out that Proellex was safer in smaller doses, they would have dodged a bullet. If indeed there were safety concerns with Proellex even in small doses, and Defendants nonetheless received financing, they might have deal with the fallout with financiers at some time in the future, but they at least would have their "stay of execution."[8] The unique timing of Repros's eleventh-hour financing attempt further supports a compelling inference of scienter.

[8] This factual scenario contrasts with *Cozzarelli v. Inspire Pharms. Inc.*, 549 F.3d 618, 627 (4th Cir. 2008), cited by Defendants. Def. Br. at 18-19. In *Cozzarelli*, the court interpreted plaintiff's motive argument that defendants knew that the success of a drug was "impossible," yet they issued positive misstatements anyway to keep the drug trials and the company alive. Plaintiffs in this Action do not allege that Proellex's success was impossible – if it was Defendants might have just quit and dissolved the Company. In fact, Defendants likely believed that Proellex could be viable in some way, and they made the misstatements in attempt to maximize the chance of survival of the Company and buy some time to work out the problems with Proellex. In fact, Repros has recently announced that they may have resolved some of the safety risks associated with Proellex and may resume testing on the 25 mg and 12.5 mg doses. However, this news has no bearing on the fact that, as alleged, during the Class Period Defendants misrepresented what was then known about Proellex's safety profile and investors were injured as a result.

III. CONTROL PERSON LIABILITY IS ADEQUATELY PLED

To state a claim under Section 20(a), the plaintiff must allege that (1) the defendant had actual power or influence over the controlled person and (2) an alleged violation by the controlled person. *Dennis v. Gen. Imaging, Inc.*, 918 F.2d 496, 509 (5th Cir. 1990). For the reasons stated above, Plaintiffs have demonstrated a primary violation under Section 10(b). Furthermore, Defendants Podolski, Ploth, and Lammers controlled Repros by virtue of their positions as Chief Executive Officer, Chief Financial Officer, and President, respectively. Accordingly, control person liability under Section 20(a) has been adequately pled.

CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss should be denied in its entirety. In the event that the Action is dismissed, Plaintiffs request leave to amend.

Dated: April 23, 2010

EMERSON POYNTER LLP

/s/ John G. Emerson

John G. Emerson, "Attorney-in-Charge"
SBOT 06602600
830 Apollo Lane
Houston, Texas 77058-2610
Telephone: (281) 488-8854
Facsimile: (281) 488-8867
E-mail: jemerson@emersonpoynter.com

Scott E. Poynter
Jack T. Patterson, SBOT 254054192
Christopher D. Jennings
Gina M. Dougherty
EMERSON POYNTER LLP
500 President Clinton Ave., Ste. 305
Little Rock, AR 72201
Telephone: (501) 907-2555
Facsimile: (501) 907-2556

Liaison Counsel

MURRAY, FRANK & SAILER LLP
Brian P. Murray *(admitted pro hac vice)*
Gregory B. Linkh *(admitted pro hac vice)*
275 Madison Avenue, 8th Floor
New York, New York 10016
Telephone: (212) 682-1818
Facsimile: (212) 682-1892

Lead Counsel

TABLE OF CONTENTS

Page

NATURE AND STAGE OF THE PROCEEDING 1

SUMMARY OF THE ARGUMENT 1

STATEMENT OF ISSUES 2

STANDARD OF REVIEW 3

FACTS 4

A. Repros's Financial Health Was Dependent on The Success of Proellex 5

B. Repros's Misstatements Regarding Proellex 6

ARGUMENT 7

I. DEFENDANTS' STATEMENTS WERE MATERIALLY FALSE AND MISLEADING 7

A. The July 1 Release 8

B. The July 7 and July 23 Releases 9

C. Cautionary Language Does Not Render Defendants' Statements Immaterial 10

II. PLAINTIFFS HAVE ESTABLISHED A STRONG INFERENCE OF SCIENTER 11

A. Defendants' Statements About the Safety Of the Smaller Doses Of Proellex Were Made Knowingly Or With Reckless Disregard For The Truth 11

B. Defendants' Consultation With A Panel Of Liver Experts Does Not Exculpate Them 13

C. The Short Time Period Between The False Statements And The Revelation Of the Truth Demonstrates Scienter 13

D. The Individual Defendants' Positions At Repros, The Small Size Of The Company, And The Fact That Proellex Was A Key Product Support An Inference Of Scienter 15

1. Proellex Was The Company's Key Product 15

2. Repros Was A Small Company 16

3. Podolski And Lammers Were Very Familiar With Proellex's Clinical Trials 16

E. Plaintiffs Have Demonstrated Additional Evidence Of Scienter Through Motive 17

III. CONTROL PERSON LIABILITY IS ADEQUATELY PLED 20

CONCLUSION 20

TABLE OF AUTHORITIES

Page

Rules and Statutes

Fed. R. Civ. P. 12(b)(6) 1, 3

Securites Exchange Act of 1934, Rule 10b-5 1

Securities Exchange Act of 1934, Section 10(b) 1, 3, 8, 20

Securities Exchange Act of 1934, Section 20(a) 1, 3, 20

Cases

Backe v. Novatel Wireless, Inc.,
642 F. Supp. 2d 1169 (S.D. Cal. 2009) 16

Bell Atl. Corp. v. Twombly,
550 U.S. 544 (2007) 3

Cozzarelli v. Inspire Pharms. Inc.,
549 F.3d 618 (4th Cir. 2008) 19

Dennis v. General Imaging, Inc.,
918 F.2d 496 (5th Cir. 1990) 20

Dura Pharms., Inc. v. Broudo,
544 U.S. 336 (2005) 4

Goldstein v. MCI WorldCom,
340 F.3d 238 (5th Cir. 2003) 19

In re Adaptive Broadband Sec. Litig.,
No. C-01-1092 SC, 2002 WL 989478 (N.D. Cal. Apr. 2, 2002) 15

In re Amylin Pharm. Inc. Sec. Litig.,
No. 01CV1455 BTM (NLS), 2003 WL 21500525 (S.D. Cal. May 1, 2003) 10

In re Connetics Corp. Sec. Litig.,
No. C. 07-02940 SI, 2008 WL 3842938 (N.D. Cal. Aug. 14, 2008) 8

In re Discovery Labs Sec. Litig.,
No. 06-1820, 2006 WL 3227767 (E.D. Pa. Nov. 1, 2006) 18

In re Genta, Inc., Sec. Litig.,
No. Civ. A. 04-2123(JAG), 2005 WL 2416970 (D.N.J. Sept. 30, 2005) 17

In re Neopharm, Inc. Sec. Litig.,
No. 02 C 2976, 2003 WL 262369 (N.D. Ill. Feb. 7, 2003) 12

In re Pfizer, Inc. Securities Litigation,
538 F. Supp. 2d 621 (S.D.N.Y. 2008) 14

In re Regeneron Pharamceuticals Sec. Litig.,
No. 94 Civ. 1785 (CLB), 1995 WL 228336 (S.D.N.Y. Mar. 10, 1995) 9

In re Regeneron Pharm. Inc. Sec. Litig.,
No. 03 Civ. 3111(RWS), 2005 WL 225288 (S.D.N.Y. Feb. 1, 2005) 11, 17

In re Seitel, Inc. Sec. Litig.,
447 F. Supp. 2d 693 (S.D. Tex. 2006) 4

In re Vertex Pharms. Inc. Sec. Litig.,
357 F. Supp. 2d 343 (D. Mass. 2005) 18

In re Viropharma, Inc.,
No. CIV. A. 02-1627, 2003 WL 1824914 (E.D. Pa. Apr. 7, 2003) 16, 17

Indiana Elec. Workers' Pension Trust Fund IBEW v. Shaw Group, Inc.,
537 F.3d 527 (5th Cir. 2008) 4, 17

Lormand v. US Unwired, Inc.,
565 F.3d 228 (5th Cir. 2009) 9

Mississippi Pub. Employees Ret. Sys. v. Boston Scientific Corp.,
523 F.3d 75 (1st Cir. 2008) 15

Nathenson v. Zonagen,
267 F.3d 400 (5th Cir. 2001) 16, 18

New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC, Inc.,
537 F.3d 35 (1st Cir. 2008) 14

Rubenstein v. Collins,
20 F.3d 160 (5th Cir. 1994) 14

Tellabs, Inc. v. Makor Issues & Rights, Ltd.,
551 U.S. 308 (2007) 4